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EXAMINER

KAUSHAL, SUMESH

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

06/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Applicant's response filed on 03/10/08 has been acknowledged and fully considered.

Claims 1-10 and 22 are pending and are examined in this office action.

*Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is **571-273-8300**.*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

Oath/Declaration

The oath or declaration stands defective for the reason of record as set forth in the office action mailed on 10/10/07. The applicant argues that the change was made by the inventor when the declaration was signed; further, the change was made adjacent to the inventor's signature and date. However the applicant's arguments are found not persuasive because non-Initialed and/or non-dated alterations have been made to the oath or declaration See 37 CFR 1.52(c). A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the purification of plasmid DNA

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and RNA in separate phases using the EO₅₀PO50 and Dextran T500 polymer based two-phase system wherein the EO₅₀PO50 and Dextran T500 polymers at concentration of 4.5% (W/W) and is in 50mM Na₂HPO₄ in desalted alkaline lysate, and wherein the adjustment of salt concentration at least 10 times above the buffer results in the separation of plasmid DNA in upper phase and RNA in lower phase, does not reasonably provide enablement for any other aqueous two-phase separation system that comprises any combination and/or concentration of polymers and salts. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The disclosure "shall inform how to use, not how to find out how to use for themselves." See *In re Gardner* 475 F.2d 1389, 177 USPQ 396 (CCPA 1973). At issue, under the enablement requirement of 35 U.S.C. 112, first paragraph is whether, given the Wands-factors, the experimentation was undue or unreasonable under the circumstances. "Experimentation must not require ingenuity beyond that to be expected of one of ordinary skill in the art." See *Fields v. Conover*, 443 F.2d 1386, 170 USPQ 276 (CCPA 1970). In the instant case the state of the art at the time of filing was such that partitioning of desalted alkaline lysate containing the plasmid DNA in an aqueous two-phase system can be influenced by different factors such as polymer concentration and salt composition. The concentration of the polymers in a two-phase system play key role in separation of plasmid DNA to the top phase. At best the specification as filed teaches that decreasing the polymer concentration in both phases a more extreme partitioning to the top phase was achieved. Qualitative analysis on an agarose gel electrophoresis shows that by decreasing the polymer concentration from 7% (w/w) Dextran T 500/7% (w/w) EO.sub.50PO.sub.50 to 4.5% (w/w) Dextran T 500 and 4.5% (w/w) EO.sub.50PO.sub.50, plasmid DNA can be partitioned to the top phase. Furthermore, it has earlier been described in the literature (Albertson, 1986) that DNA can effectively be transferred between phases only by addition of suitable salts. To achieve a dominating effect of the salt in a two-phase system, the concentration of the salt must be at least ten times higher than the buffer. The addition of a salt to a two-

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phase system forces the anion and the cation to partition together between the two different polymer phases and this will generate an electrical potential between the phases. For example the HPO_4^- anion has affinity for the dextran phase. This will create an electrochemical driving force in the system. If a negatively charged substance e.g. plasmid DNA is added to this system, the DNA will partition to the top phase. See instant specification Page 17-18.

The USPTO does not have laboratory facilities to test if an invention will function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raised and discussed based on the state of knowledge pertinent to an art at the time of the invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of skill. In instant case phase-separation of DNA and RNA using any and all kind of polymers in a solution having any salt concentration is not considered routine in the art and without sufficient guidance to a specific polymer(s) in an aqueous two-phase system with known salt effects the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See Ex parte Singh, 17 USPQ2d 1714 (BPAI 1991). Therefore considering the state of the art and limited amount of guidance provided in the instant specification, one skill in the art would have to engage in excessive and undue amount of experimentation to practice the invention as claimed.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sumesh Kaushal
Primary Examiner
Art Unit 1633

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